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Express Mail No. EV 346 810 728 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Irun R. COHEN et al.

Confirmation No.: 5950

Application No.: 10/032,482

Group Art Unit: 16423

Filing Date: January 2, 2002

Examiner: L. Helms

For: IMMUNOGENIC COMPOSITIONS FOR
INDUCTION OF ANTI-TUMOR ACTIVITY

Attorney Docket No.: 85189-700

RESPONSE TO RESTRICTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the office action dated March 1, 2004, please enter the following comments into the file of this application.

Claims 1-11 remain in this application. In response to the Examiner's restriction requirement, applicants provisionally elect, with traverse, Group XXXII, namely claims 8-11 drawn to a peptide of SEQ ID NO: 21 (Peptide V: Tyr-Tyr-Cys-Gln-His-Ile-Arg-Glu-Leu-Thr-Arg-Ser-Glu-Gly-Gly-Pro Ser or SEQ ID NO:21) for prosecution in this application. It is respectfully submitted, however, that the restriction requirement is in error and should be withdrawn so that all aspects of the claims are examined together in this application.

The number of restrictions appear to be unjustified in view of the format of the present claims. These claims are directed to immunogens (the peptides of claims 8-11) or methods of administering the same (claims 1-7) for induction of anti-tumor immunity in mammals, for activating an enhanced immune response to a p53 molecule in mammals, and for induction of immune responses to mutated and wild-type forms of a p53 in mammals. The immunogen can be any one of (i) an anti-p53 mAb; (ii) a fragment of an anti-p53 mAb; (iii) a peptide based on a CDR of the heavy or light chain of an anti-p53 mAb, which peptide is capable of eliciting antibodies to p53; and (iv) a DNA molecule coding for the variable (V) region of an anti-p53 mAb in a suitable gene delivery vehicle. The present invention thus

encompasses the use of any anti-p53 mAb, or a fragment thereof. According to the present invention, anti-p53 mAbs to either native or mutant p53 can serve as immunotherapeutic agents of wide applicability in the treatment of cancer. The therapeutic anti-p53 mAbs can be of various kinds, including murine, human, or "humanized" mouse antibodies, all of them isolated or prepared in different ways by standard procedures.

The specific peptides that are identified each enable and support the patentability of the generic peptide and method claims. While the applicants do not object to the Examiner's requirement of an election of a particular peptide to assist in conducting a search of the art, a 36 way restriction of different inventions is unjustified. The peptides and methods of use are not independent and distinct, but bear a relation to each other such that a proper search of the peptide claims would obtain art relating to the use of the peptides as well, while a search of the specific methods recited would certainly include an identification of any peptides that are used in such methods.

In addition, it should be noted that this application is a division of a US national stage application that is based on a PCT International application. Unity of invention is covered under the applicable WIPO rules, to which of course the US subscribes. The national stage filings of an International application are governed by the same conditions as the International application, and are more particularly defined by the guidelines given in the PCT gazette of June, 1998, (see Code of Federal Regulations, Title 37, §1.475).

The requirement of unity of invention is fulfilled for a group of inventions that are so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention is fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The guidelines further go more in detail regarding the requirement of unity in the case of the application of the "Markush doctrine" wherein only one claim defines variable chemical structures, and which is also governed by Article 13.2 PCT. In that particular case, the condition relative to the existence of a technical relationship and to the presence of the same of corresponding special technical features as set forth in rule 13.2 should be considered as fulfilled when the variant chemical structures are of "analogous nature".

Generally, various chemical structures are considered to be of analogous nature when they meet the following criteria:

A) all the variant structures have a common property or activity, and
B1) all the variant structures have an important structural element in common, or

B2) all the variant structures belong to an "accepted" class of chemical compounds in the field of the invention, i.e., that it is possible to replace each element by another one, relying on the same result.

In the particular case of the invention, condition A) is certainly met, since each peptide has the same property, namely, that is capable of eliciting antibodies to p53. B2) is fulfilled since all compounds are peptides, and B1) is fulfilled because each peptide is based on a CDR of the heavy or light chain of an anti-p53 mAb.

Regarding the Examiner's comments regarding a separate search, it is noted that each peptide of Groups XX through XXXVI are classified in class 530, subclass 3000, while each of the methods of Groups I through XIX are classified in class 514, subclass 2. It is not seen how the review of a limited number of classes and subclasses creates an additional undue searching burden on the Examiner, in particular because a proper search of the invention requires that all peptides based on a CDR of the heavy or light chain of an anti-p53 mAb that are capable of eliciting antibodies to p53 must be reviewed in order to determine if the independent claims are patentable. As a search of any such peptide should be made, the search results can easily be compared to the 17 specific peptides that are listed to enable and support applicants' generic claims. In addition, as to the specific sequences recited, these are readily searchable electronically through the PTO database of sequence listings.

Thus, the Examiner's reconsideration and withdrawal of the restriction requirement is respectfully solicited. Furthermore, the election made above is solely for the purpose of assisting the Examiner in defining an initial search. As the Examiner is well aware, if material prior art against the elected peptide is not located, then the search should be expanded in an attempt to determine if any of the other peptides that are recited in the claims are disclosed in the art.

Applicants appreciate the Examiner's comments regarding rejoinder of process claims after the allowance of product claims. For this reason all original claims are maintained in the application. It is respectfully submitted that upon the allowance of peptide claim 8, applicants will amend method claims 1-4 to depend from or otherwise include all the recitations of the patentable product so that those claims will also be allowable.

As the current claims are patentably distinct from the prior art that has been cited, it is believed that the entire application is now in condition for allowance, early

notification of such would be appreciated. The Examiner is respectfully invited to contact the undersigned attorney of record for a personal or telephonic interview to discuss any issues if such procedure would expedite the eventual allowance of the claims.

No fee is believed to be due for the submission of this response. Please charge any required fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

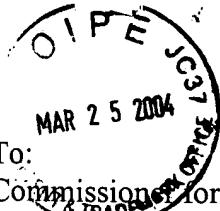
3-25-04
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212-294-3311



EXPRESS MAIL LIST

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The following items listed below are being filed herewith with the USPTO on March 25, 2004

Express Mail No. **EV 346 810 728 US**

Attorney Docket No.	Appln. Serial No./ Patent No.	Items - Documents filed on March 25, 2004
85189-700	10/032,482	Response to Restriction (4 pages)

*Please acknowledge receipt of these items as received by returning
the enclosed postcards with the date of receipt of March 25, 2004*

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